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# Effects of a Multifaceted Psychiatric Intervention Targeted for the Complex Medically Ill: A Randomized Controlled Trial

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## Key Words

Case complexity • INTERMED • Consultation-liaison psychiatry • Depression • Psychiatric intervention • Randomized controlled trial

## Abstract

**Background:** This study evaluated a multifaceted psychiatric intervention targeted at the complex medically ill identified by means of the INTERMED, an instrument to assess case complexity. **Methods:** Of 885 rheumatology inpatients and diabetes outpatients who were assessed for eligibility, 247 were identified as complex (INTERMED score >20) and randomized to the intervention (n = 125, 84 rheumatology and 41 diabetes patients) or care as usual (n = 122, 78 rheumatology and 44 diabetes patients). For the majority of the cases the multifaceted intervention consisted of an intervention conducted by a psychiatric liaison nurse and/or of referral to a liaison psychiatrist, followed by advice to the treating physician or organization of a multidisciplinary case conference. Baseline and follow-up at months 3, 6, 9 and 12 measured prevalence of major depression (Mini-International Neuropsychiatric Interview), depressive symptoms (Center for Epidemiological Studies Depression Rating Scale), physical and mental health (SF-36), quality of life (EuroQol), health care

utilization and HbA<sub>1c</sub> levels (diabetic patients). **Results:** Prevalence of major depression was reduced from 61% (T0) to 28% (T4) in the intervention group and remained stable in care as usual (57% at T0 to 50% at T4). Compared to care as usual, significant improvement over time was observed in the intervention group with regard to depressive symptoms (F = 11.9; p = 0.001), perception of physical (F = 5.7; p = 0.018) and mental health (F = 3.9; p = 0.047) and quality of life (F = 21.8; p < 0.001). Effects tended to be stronger in diabetes patients, in patients with baseline major depression and in patients with moderate INTERMED scores. Finally, hospital admissions occurred less often in the intervention group, reaching statistical significance for the period between 6 and 9 months of follow-up (p = 0.02). **Conclusions:** The results suggest that a psychiatric intervention targeted for complex medical patients can improve health outcomes.

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## Introduction

Up to 30% of patients in the general hospital suffer from clinically relevant psychiatric comorbidities [1, 2]. Such patients have high levels of functional impairment [3, 4], a longer hospital stay [3, 5], increased health care

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utilization [3, 6], a diminished response to medical treatments [7, 8] and a reduced quality of life, independent of the severity of the physical illness [9].

Consequently, psychiatric intervention studies have been conducted with the aim to improve health outcome in patients with somatic and psychiatric comorbidities [8, 10, 11]. While some of these studies demonstrated a beneficial effect on psychosocial and medical outcomes [12–14] and health care utilization [15, 16], others showed only minor or no effects [17]. Authors reviewing these studies repeatedly criticized that they were not targeted at high risk patients, not conducted as randomized controlled trials and lacked adequate follow-up [18].

To target interventions is important in psychiatry and especially in consultation-liaison psychiatry, since most of the consultations are requested in emergency situations, late in the course of the hospitalization and for patients with overt behavioral disturbances [19]. Such consultations are rather oriented towards the needs of clinicians than of patients [19]; psychiatric interventions in the medically ill should therefore be based on indicators reflecting patient needs.

Based on our previous work [8, 20–29], we hypothesize that not psychiatric diagnosis or psychopathology per se but the resulting case complexity is most important to explain variance between patients with regard to medical outcome and quality of life. Case complexity or ‘case mix’ refers to the characteristics which describe how patients with similar types and stages of disease vary in their health care needs and utilization. Case complexity is determined by diagnosis but also by a variety of other parameters, such as chronicity, severity of illness, cognitive problems or depression [20, 21, 29]. Over the last decade, an empirically based, valid and reliable instrument to assess bio-psycho-social case complexity and resulting care needs, the INTERMED, has been developed [22–24, 29]. The INTERMED has been shown to identify complex patients with a diminished response to medical treatments in various populations, such as patients admitted to internal medicine [21], patients with low back pain [26], diabetes [27], rheumatoid arthritis [25] or cancer and multiple sclerosis [29].

The main objective of this study was to evaluate the benefits of targeting a psychiatric intervention for the complex medically ill, identified by means of the INTERMED.

## Methods

After approval by the ethics committee of the University Hospital of Lausanne, the study started in November 2002, the last follow-up ended in April 2006. Screening for eligibility and inclusion was performed by 3 psychiatric liaison nurses (F.B.H., D.B. and C.Z.); 2 nurses (F.B.H. and D.B.) provided the intervention and 1 (C.Z.), blinded to randomization, conducted follow-up assessments.

### Patients

A total of 885 patients from 2 different populations were approached for inclusion in the study: (i) 229 patients with diabetes (25.9%) – the majority of whom classified as type 2 diabetes ( $n = 156$ ; 68.1%) – consulting the outpatient clinic of the Division of Endocrinology and Metabolism and (ii) 656 (74.1%) patients admitted to the inpatient unit of the Rheumatology Service of the University Hospital of Lausanne. Rheumatology inpatients were classified as having inflammatory diseases (such as chronic polyarthritis), degenerative diseases (such as arthrosis and chronic pain), age-related diseases (such as osteoporosis) and other diseases (such as fibromyalgia). Diabetes patients were subdivided as having type 1, type 2 or another form of diabetes.

### Study Design and Randomization

Patients with the following exclusion criteria were not eligible: not speaking French, severe cognitive disturbances, terminal illness, planned placement in an institution, hospitalization for <3 days and suicidal risk. Eligible patients were included and, if identified as complex, randomized to the intervention or care as usual by means of a computer-generated list.

### Assessments

*Sociodemographic and medical characteristics:* Age, sex, educational and professional status, as well as the above-mentioned medical diagnoses and strata of the rheumatology patients were recorded at baseline.

*INTERMED/case complexity:* All eligible patients were screened for case complexity by means of the INTERMED (see fig. 1). The INTERMED is an observer-rated instrument, which classifies information from a medical history-taking into 4 domains: biologic, psychological, social and health care. In each of the 4 domains 5 variables, related to ‘history’, ‘current state’ and ‘prognosis’, are rated 0–3 according to a manual with clinical anchor points, resulting in a potential score range of 0–60 (a higher score indicates an increase in case complexity). The ratings are not specific but generic and apply to any somatic disease. A trained nurse can conduct and reliably rate the INTERMED interview within 15 min. Based on a cutoff score of >20 for identification of case complexity, the INTERMED was found to have good inter-rater reliability ( $\kappa = 0.85$ ), test-retest reliability with a period of 1 year between ratings ( $r = 0.75$ ;  $\kappa = 0.60$ ) and internal consistency (estimated Cronbach’s  $\alpha$  ranging between 0.78 and 0.94 in several samples of patients with somatic illnesses) [29]. The French version of the INTERMED was previously standardized by the first author (F.S.), who co-developed the INTERMED [30].

Presence of current *major depression* was assessed by means of the validated French version [31] of the depression section of the Mini-International Neuropsychiatric Interview (MINI) [32], a standardized interview which can be conducted by a trained

**Fig. 1.** The INTERMED scoring grid, copyright 1999 (Elsevier Science). For more information: [www.intermedfoundation.org](http://www.intermedfoundation.org) [30]. Examples from the INTERMED scoring manual: premorbid psychiatric dysfunction (history): 0 = no history of psychiatric dysfunction; 1 = a history of psychiatric dysfunction without effects on daily functioning; 2 = a history of psychiatric dysfunction with an impact on daily functioning; 3 = a history of at least 1 psychiatric inpatient admission; x = unknown, no information available.

|                      | History   | Current state   | Prognosis                     |
|----------------------|---|---|-------------------------------|
| <b>Biological</b>    | Chronicity<br>Diagnostic complexity                         | Severity of illness<br>Diagnostic complexity                          | Complications and life threat |
| <b>Psychological</b> | Restrictions in coping<br>Premorbid psychiatric dysfunction | Resistance to treatment<br>Severity of psychiatric symptoms           | Mental health threat          |
| <b>Social</b>        | Restrictions in social integration<br>Social dysfunctioning | Residential instability<br>Restrictions of social network             | Social vulnerability          |
| <b>Health care</b>   | Intensity of prior treatment<br>Prior treatment experience  | Organizational complexity<br>Appropriateness of admission or referral | Care needs                    |

layperson and assesses the presence of a research diagnosis of several psychiatric disorders according to the criteria of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IVR) [33].

*Depressive symptoms* were assessed by means of the Center for Epidemiological Studies Depression Rating Scale (CES-D) [34]. The CES-D is a 20-item self-report scale developed to measure the severity of depressive symptoms. Subjects are asked how often they experienced each symptom during the last week; items are scored on a 4-point scale, ranging from 0 (rarely or never) to 3 (most of the time). The total CES-D score ranges from 0 to 60, a score >16 indicates a clinically relevant depression [34]. The overlaps with symptoms originating from a physical illness are limited; the CES-D has been proved to be a valid instrument in the physically ill [35], including patients with rheumatoid arthritis [36] and diabetes [37].

*Physical and mental health* was measured with the validated French version [38] of the SF-36 [39]. The SF-36 consists of 36 items, organized into 8 scales (physical functioning, social functioning, role limitations – physical, pain, mental health, role limitation – emotional, vitality and general health) [39]. The scales are recorded into standardized scores, subsequently used to construct 2 summary scores: a Physical Health Component Score (PCS) and a Mental Health Component Score (MCS), based on the factors found by Hays and Stewart [40], with a scoring range between 0 and 100 (100 = optimal functioning). The SF-36 has been proven to be a practical tool to measure self-assessed physical and mental functioning in the medically ill, including patients with rheumatoid arthritis and related disorders [41] and diabetes [42].

*Health-related quality of life* was assessed with the validated French version [43] of the Visual Analogue Scale (0–100, a higher score indicating a higher quality of life) of the EuroQoL. The EuroQoL has been used in many studies with the medically ill, including patients with rheumatoid arthritis and related disorders [44] and diabetes [45].

#### Intervention

The control group received care as usual, which includes the possibility for the treating physician to request a psychiatric con-

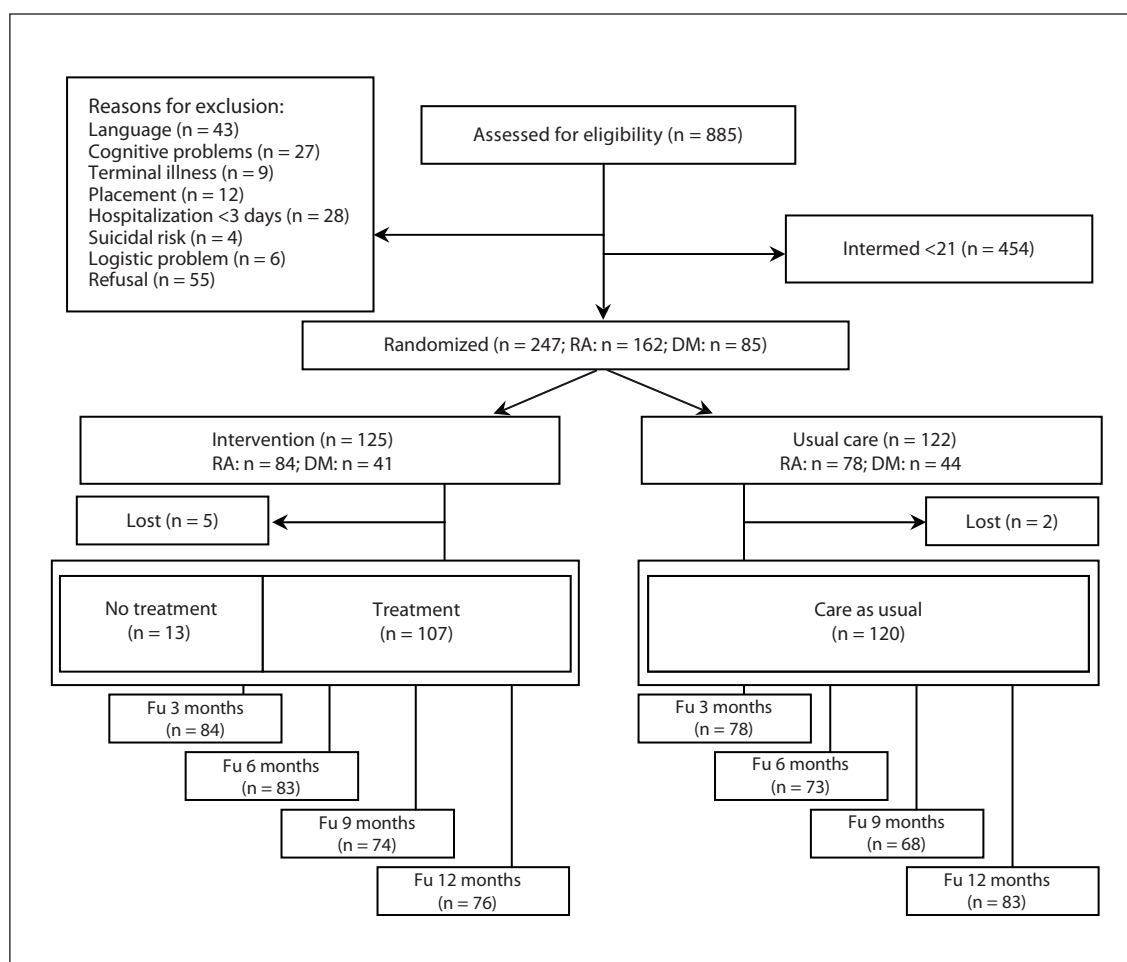
sultation; both somatic services involved in this study have access to liaison psychiatry and regularly refer patients. The intervention was designed as a multifaceted intervention in order to allow different approaches and to involve different health care professionals depending on the clinical situation of the patient. Three different interventions, single or combined, were proposed by a psychiatric liaison nurse: (i) supportive counseling focused on coping with disease and compliance with treatment, effectuated by the psychiatric liaison nurse; (ii) referral of the patient to a liaison psychiatrist, and (iii) advice to the treating physician or organization of a multidisciplinary case conference attended by the treating physicians and nurses, and a liaison psychiatrist.

#### Follow-Up

Outcome was documented every 3 months during a 1-year follow-up by the psychiatric research nurse (C.Z.), who was blinded to the intervention. Follow-up consisted of baseline measures (except for the medical and sociodemographic characteristics and the INTERMED) and health care utilization, based on a methodology used in prior studies [25–27]: patients are asked to document in a booklet days of hospitalization, visits to a specialist or a general practitioner, emergency room visits and paramedical consultations covered by health insurance. The patients answered the questionnaires by mail; if they did not respond, the research nurse collected the information during a telephone interview. For diabetes patients, HbA<sub>1c</sub> levels were recorded by chart review.

#### Statistical Analyses

Effects of intervention were evaluated with regard to (a) prevalence of major depression (MINI); (b) depressive symptoms (CES-D); (c) physical health (PCS); (d) mental health (MCS), and (e) quality of life (QoL). We applied a repeated measurements analysis using the SPSS mixed model approach, since outcomes were assessed repeatedly during the follow-up at 3, 6, 9 and 12 months after randomization. An advantage of this approach is that optimal use is made of the available data at the repeated assessments, which are clustered within subjects [46]. Moreover,



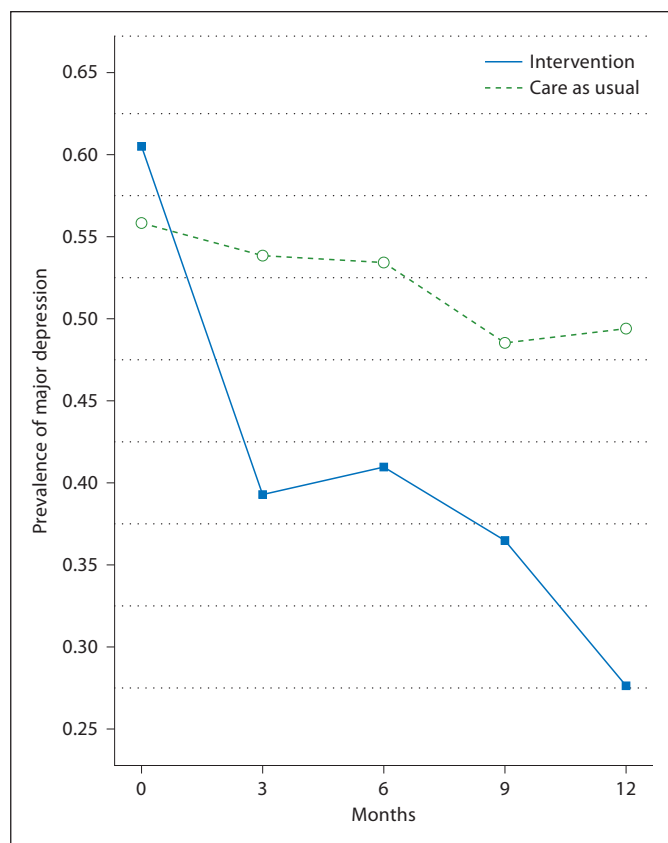
**Fig. 2.** Patient flow chart. RA = Rheumatoid arthritis; DM = diabetes mellitus; Fu = follow-up.

this analysis allows to evaluate differential change over time between treatment arms on the outcomes. Also, this analysis limits the number of comparisons, thereby reducing the chance of spurious findings. To evaluate treatment effects, we developed mixed models for each of the 4 outcomes with continuous distributions (CES-D, PCS, MCS, QoL) consisting of treatment allocation as a factor, the corresponding baseline variable and the timing of the assessment. The following preplanned subgroup analyses were conducted to further pin down the effects of the intervention: (1) rheumatology patients versus diabetes patients; (2) patients with versus without major depression at baseline, and (3) patients with INTERMED scores 20–30 versus >30. For these subgroup analyses, mixed models using the CES-D as outcome were applied, and subgroup membership (i.e. rheumatology or diabetes) and its interaction with treatment condition as covariates was added.

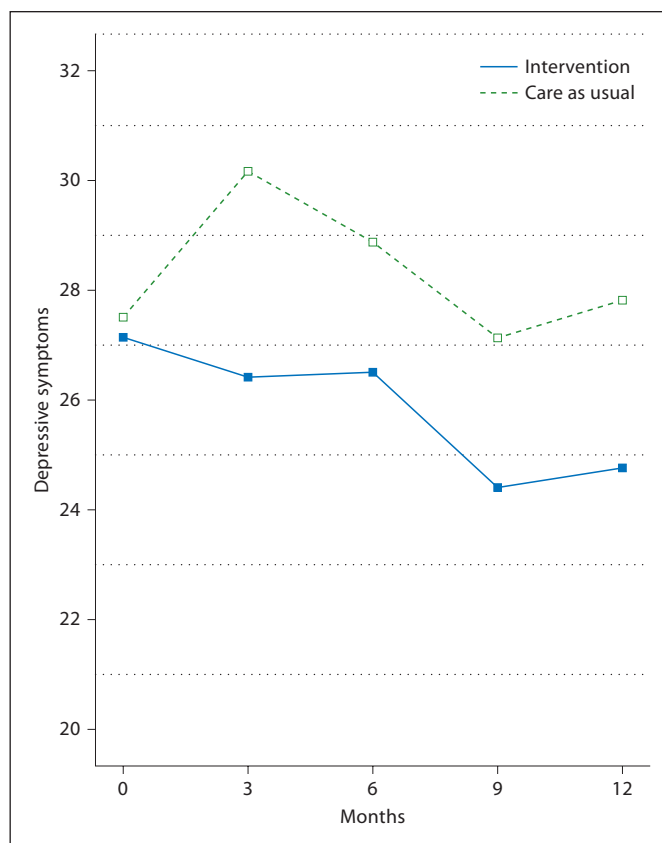
## Results

Of the 885 patients assessed for eligibility (see fig. 2), 184 (20.8%) met exclusion criteria, such as not speaking French (n = 43), severe cognitive disturbances (n = 27) or hospitalization for <3 days (n = 28); 6.2% refused to participate (n = 55). Of the remaining patients (n = 701), 64.8% (n = 454) did not qualify as complex patients (INTERMED score <20). The remaining 247 patients were randomized, 125 (84 rheumatology inpatients and 41 diabetes outpatients) to the intervention and 122 to care as usual (78 rheumatology inpatients and 44 diabetes outpatients). With regard to sociodemographics (age, sex, educational and professional status) and baseline measurements (including the above-mentioned strata of the rheumatology patients and the different types of diabetes), the intervention and care as usual groups did not





**Fig. 3.** Effects on prevalence of major depression (MINI).



**Fig. 4.** Effects on depressive symptoms (CES-D).

differ at baseline. Based on the MINI, more than half of the sample (61% of the intervention group and 56% of the care as usual group) qualified for a diagnosis of major depression.

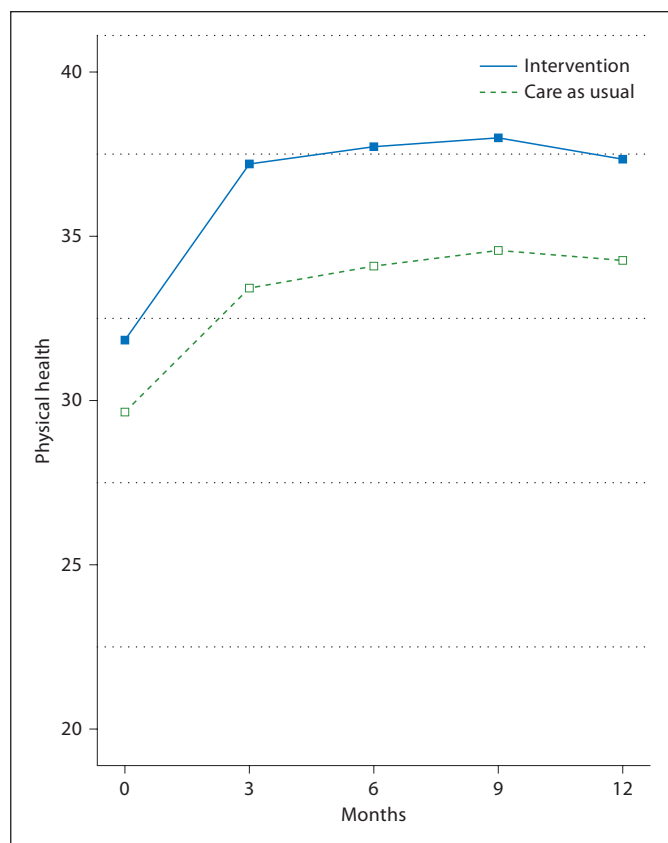
In the intervention arm, most patients ( $n = 107$ ) received an intervention conducted by the psychiatric liaison nurse; the interventions, effectuated as single interventions or combined, consisted of 'facilitating emotional expression' (73%), 'practical advice' (71%), 'promoting life narrative' (48%) and 'psychoeducational interventions' (44%). For about half of the patients in the intervention group ( $n = 76$ ) also other types of intervention were proposed, such as referral to a liaison psychiatrist ( $n = 36$ ), psychiatric advice to the treating physician ( $n = 32$ ) or interdisciplinary case conferences ( $n = 8$ ). A minority of patients ( $n = 13$ ) did not receive any treatment (due to a lack of indication for a psychosocial intervention or patient lacking motivation). The liaison nurses, who effectuated the intervention, were supervised weekly by a senior psychiatrist (F.S.) or an experienced psychiatric liaison nurse (Y.D.).

Between 62 and 70% of the patients of the intervention arm and between 57 and 69% of the patients of the usual care arm provided complete follow-up data at the 4 time points (see fig. 2). Patients with missing data did not differ from patients with complete data with regard to age, sex, educational and professional status, baseline quality of life and depression on each of the 4 follow-up assessments.

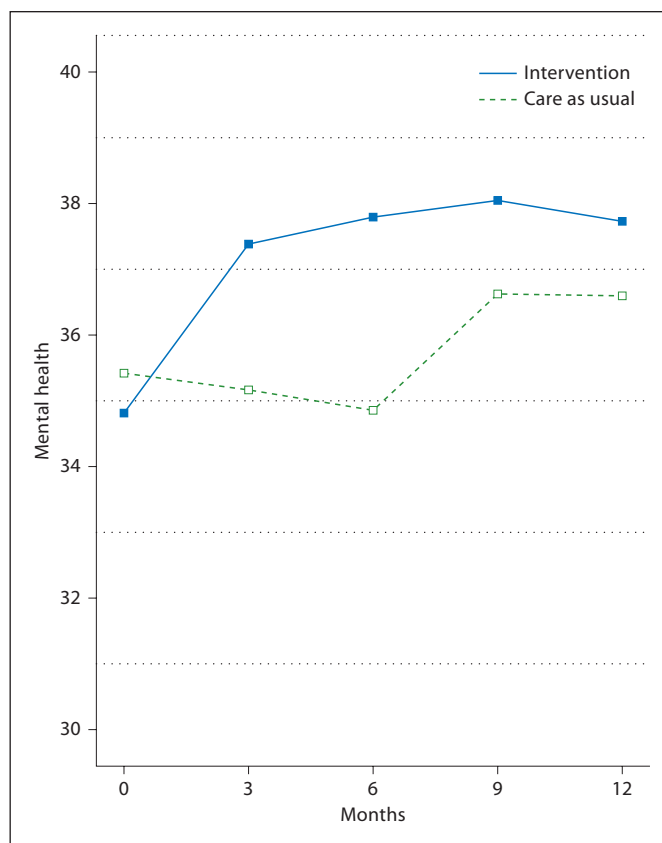
#### *Effects of Intervention*

In figures 3–7, comparisons between patients in the intervention arm and usual care arm on the main outcomes are presented. Overall, the intervention was associated with less depression and higher levels of quality of life during follow-up.

Mixed model analyses of these data resulted in the following observations: controlling for baseline CES-D and timing of assessment, intervention is associated with 3.0 (s.e. = 0.9) points less on CES-D ( $F = 11.0$ ;  $p = 0.001$ ). Controlling for baseline PCS and timing of assessment, intervention is associated with a 1.6 (s.e. = 0.7) higher score on



**Fig. 5.** Effects on physical health (PCS).



**Fig. 6.** Effects on mental health (MCS).

PCS ( $F = 5.8$ ;  $p = 0.02$ ). Controlling for baseline MCS and timing of assessment, intervention is associated with a 2.5 (s.e. = 1.0) higher score on MCS ( $F = 6.6$ ;  $p = 0.01$ ). Controlling for baseline QoL and timing of assessment, intervention is associated with a 7.8 (s.e. = 1.6) higher score on QoL ( $F = 23.7$ ;  $p < 0.001$ ).

Health care utilization did not differ between the groups, except for percentage of hospitalized patients over the follow-up period, which differed in favor of the intervention, reaching significance at month 9 (fig. 8). For only 15 patients in the intervention and 13 patients in the care as usual arm at least a baseline and 1 follow-up HbA<sub>1c</sub> was documented; this did not allow a meaningful statistical analysis.

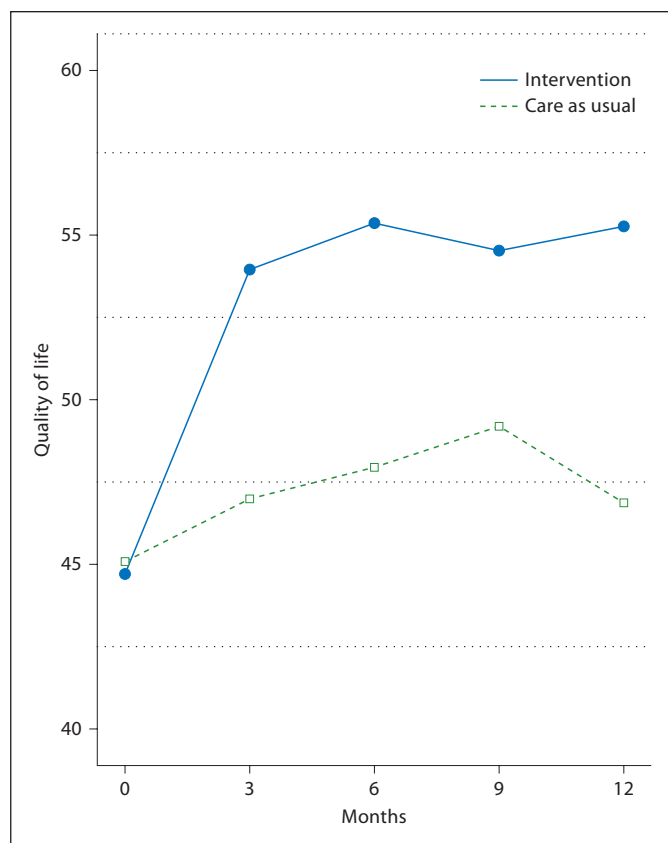
#### Subgroup Analyses

Using mixed model analyses, the effects of intervention on CES-D scores tended to be stronger in diabetes patients [effect size: 5.2 (s.e. = 1.5);  $p = 0.001$ ] than in rheumatology patients [effect size: 1.7 (s.e. = 1.1);  $p = 0.14$ ]; this interaction effect was marginally significant

( $p = 0.065$ ). Larger effects were found in patients with a baseline major depression [effect size: 4.1 (s.e. = 1.2);  $p = 0.001$ ] than without [effect size: 1.6 (s.e. = 1.4);  $p = 0.26$ ]; however, the interaction term was not significant ( $p = 0.18$ ). Finally, larger effects were also observed in patients with an INTERMED score 20–30 [effect size: 2.5 (s.e. = 1.0);  $p = 0.01$ ] than >30 [effect size: 1.2 (s.e. = 2.1);  $p = 0.59$ ]; this interaction term was not significant either ( $p = 0.59$ ).

#### Discussion

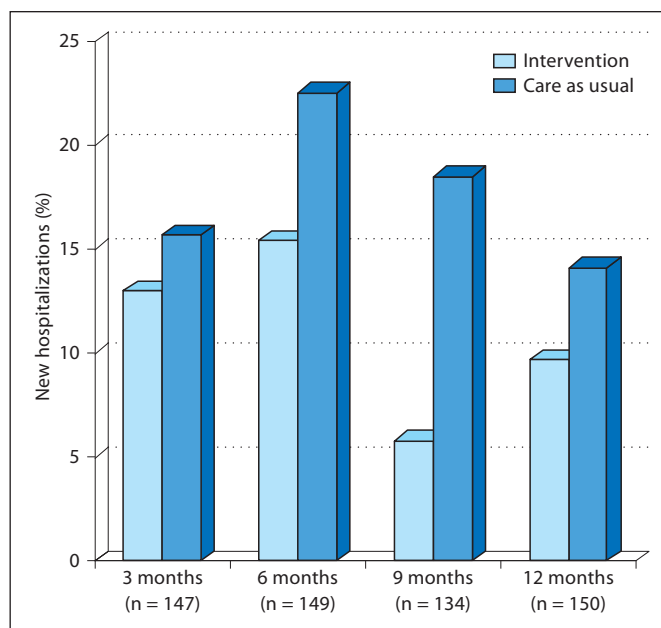
Of the patients screened with the INTERMED, 35% qualified as complex (cutoff >20). This prevalence is in line with previous reports [47] and confirms the utility of the INTERMED as a screening instrument for case complexity, even in a selected population of patients of a tertiary care center suffering from chronic conditions, known to be associated with an important psychiatric comorbidity [48, 49].



**Fig. 7.** Effects on quality of life.

The high prevalence of major depression in complex patients (more than half of the sample at baseline) underlines the already observed strong association between depression and case complexity, which may influence each other [50]. Other investigators found about half of these prevalence rates of depression in patients with diabetes and rheumatological disorders [48, 49]; however, these were overall prevalence rates, while the prevalence of major depression in this study concerns a selected minority of complex patients. Despite the fact that the MINI is a validated instrument to provide a research diagnosis of major depression, we cannot exclude that a clinical interview by a psychiatrist would have led to a lower prevalence rate of major depression due to positively screened patients with adjustment disorders, minor depression and subthreshold depressive disorders.

The multifaceted psychiatric interventions described above were organized by psychiatric liaison nurses. Patients who needed further assessment or psychopharmacological treatment were referred to a liaison psychiatrist or advice, for example with regard to psychopharmaco-



**Fig. 8.** Effects on new hospitalizations. T3:  $p = 0.64$ ; T6:  $p = 0.26$ ; T9:  $p = 0.02$ ; T12:  $p = 0.41$ .

logical treatment or general management, was provided to the treating physician. Since we had not anticipated such a high prevalence of depression, psychopharmacological treatment was not recorded; therefore we are not able to firmly identify the specific 'beneficial elements' of the intervention. It might be that psychopharmacological treatment was more frequently utilized in the intervention group, due to referral to a liaison psychiatrist or advice given to treating physicians. Interdisciplinary case conferences were rarely organized, mainly due to the lack of time of the medical staff.

The intervention was effective with regard to different outcomes. Prevalence of major depression decreased in the intervention group; at 12 months of follow-up it was reduced from  $>50\%$  at baseline to  $<30\%$ , while in care as usual it remained almost stable. Similarly, in the intervention arm depressive symptoms consistently decreased over time, while in care as usual they remained stable or tended to increase. Prior studies on the treatment of depressive symptoms in the medically ill did not always result in a significant effect, perhaps because many interventions were not targeted for specific subgroups of patients [51, 52].

Perception of physical health improved in both groups, mainly within the first 3 months; however, this increase over time was consistently in favor of the intervention.



Perception of mental health also improved over time, with significant improvement for the intervention group compared to care as usual, but this difference reached a peak at 3–6 months of follow-up. With regard to quality of life, a similar result was found, with a constant difference favoring the intervention arm over the whole follow-up period of a year. Taken together, these results confirm that this targeted psychiatric intervention reduced emotional distress and improved health perception and quality of life. These results are important in view of the fact that the INTERMED interview, conducted in both groups, may have a therapeutic effect by itself; in prior studies, patients were very positive about being interviewed with the INTERMED [27], a finding which was specifically confirmed in a recent study [53].

Medical outcome with regard to health care utilization did not differ between the groups, except for the percentage of patients who had to be hospitalized; fewer patients of the intervention group were hospitalized during each 3-month period of the follow-up, reaching a significant difference between months 6 and 9.

The benefits of the intervention may be due to more frequent and earlier detection and treatment of psychosocial problems. A prior study with the INTERMED based on psychiatric liaison nurse interventions only resulted in a significant effect on quality of life of a subgroup of elderly patients; however, the interventions were not targeted and closer to hospital-based case management than to a psychiatric intervention [47]. The fact that the INTERMED can be considered as an instrument which is more inspired by ‘clinimetrics’ and ‘communitrics’ than ‘psychometrics’ may also explain these benefits [54]. In addition, the INTERMED allows, in contrast to case management and disease management plans, not only to assess bio-psycho-social case complexity but also to direct individualized care [55]. Ouwers et al. [56], who discussed 13 systematic reviews of integrated care programs for chronically ill patients, found that only 1 review reported a significant positive effect on functional health status and only 3 reported a significant positive effect on hospital readmissions or length of stay.

Subgroup analyses revealed a different impact of the intervention with regard to depressive symptoms, medical diagnosis, presence of major depression and INTERMED scores. The more beneficial effect of the intervention in diabetes patients may be due to their status as outpatients and a less important burden of disease but also to the stratum of ‘degenerative diseases’ of the rheumatology patients; in this stratum were included patients hospitalized for pain, often chronic pain and somatoform

disorders, thus difficult to treat both from a physical and psychological point of view. Improvement of outcome in patients with a presence of major depression at baseline is not a spectacular finding, since improvement of major depression has most probably influenced the other outcome variables. Patients with a high degree of case complexity might have benefited less, since such patients are often in a chronic state with regard to their physical, psychological and social situation, which is difficult to influence; a finding which is confirmed by prior studies with the INTERMED [26]. However, these results are all based on subgroup analyses and should be considered as hypothesis-generating only.

Two randomized controlled trials have assessed the effectiveness of implementing psychiatric interventions on general medical wards by means of standard screening for psychiatric symptoms and subsequent treatment [57, 58]. In the first study [57], no evidence for a reduction in length of hospital stay, hospital-based or post-discharge costs upon follow-up was found. In the second study [58], no evidence was found for an improvement of mental health status, quality of life or costs upon follow-up. The results of this study support the strategy to utilize the INTERMED to screen and assess case complexity and to orient patient care. The INTERMED is already utilized on a routine basis in different clinical settings [55]; this study confirms these clinical experiences and adds evidence with regard to the validity of the INTERMED.

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